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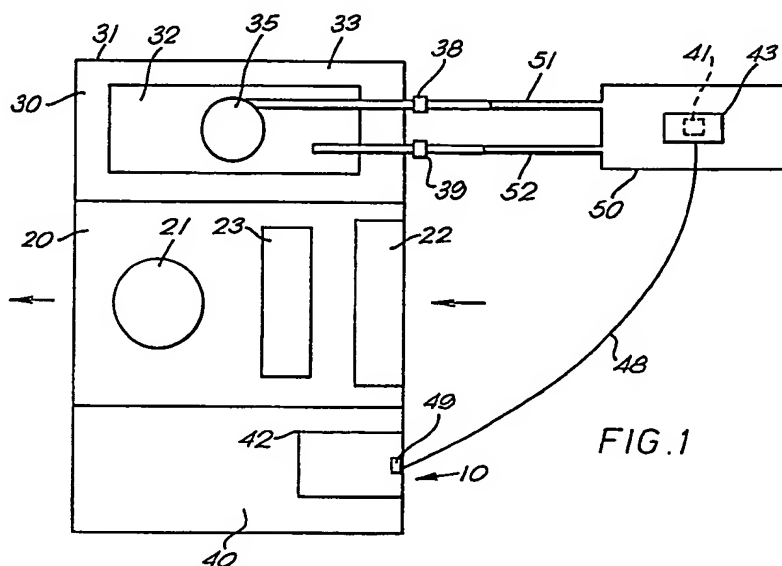
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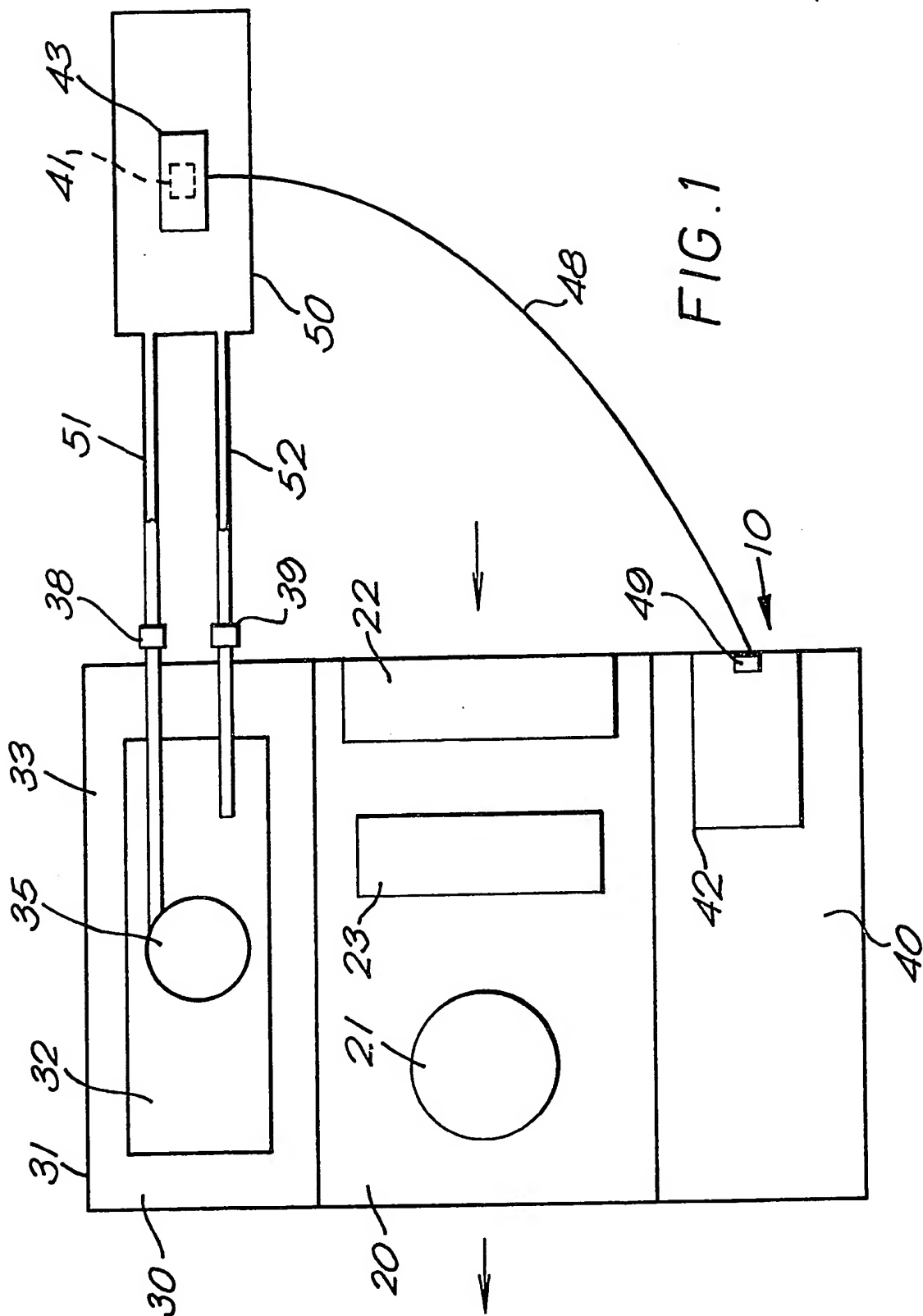
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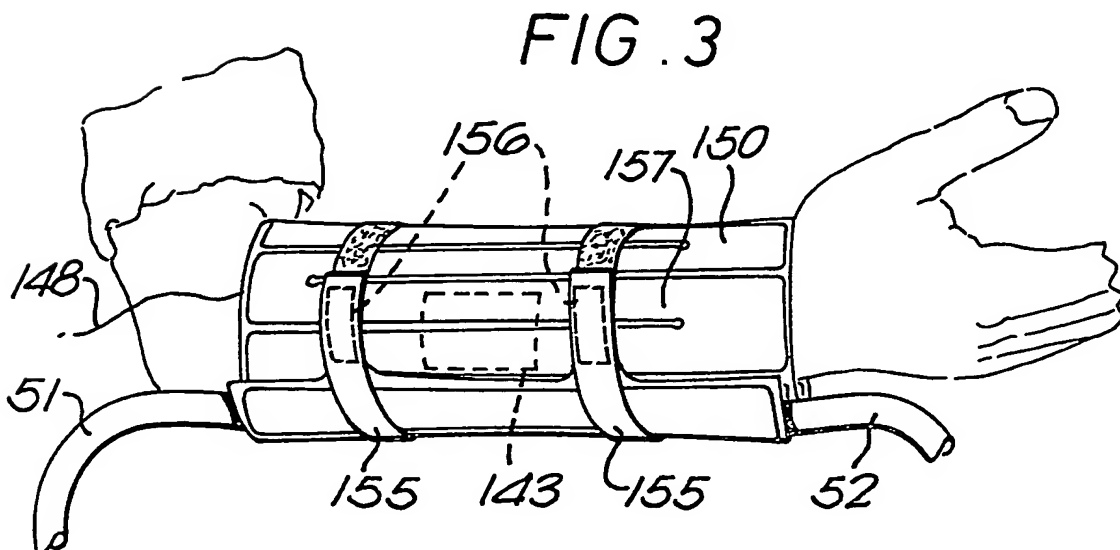
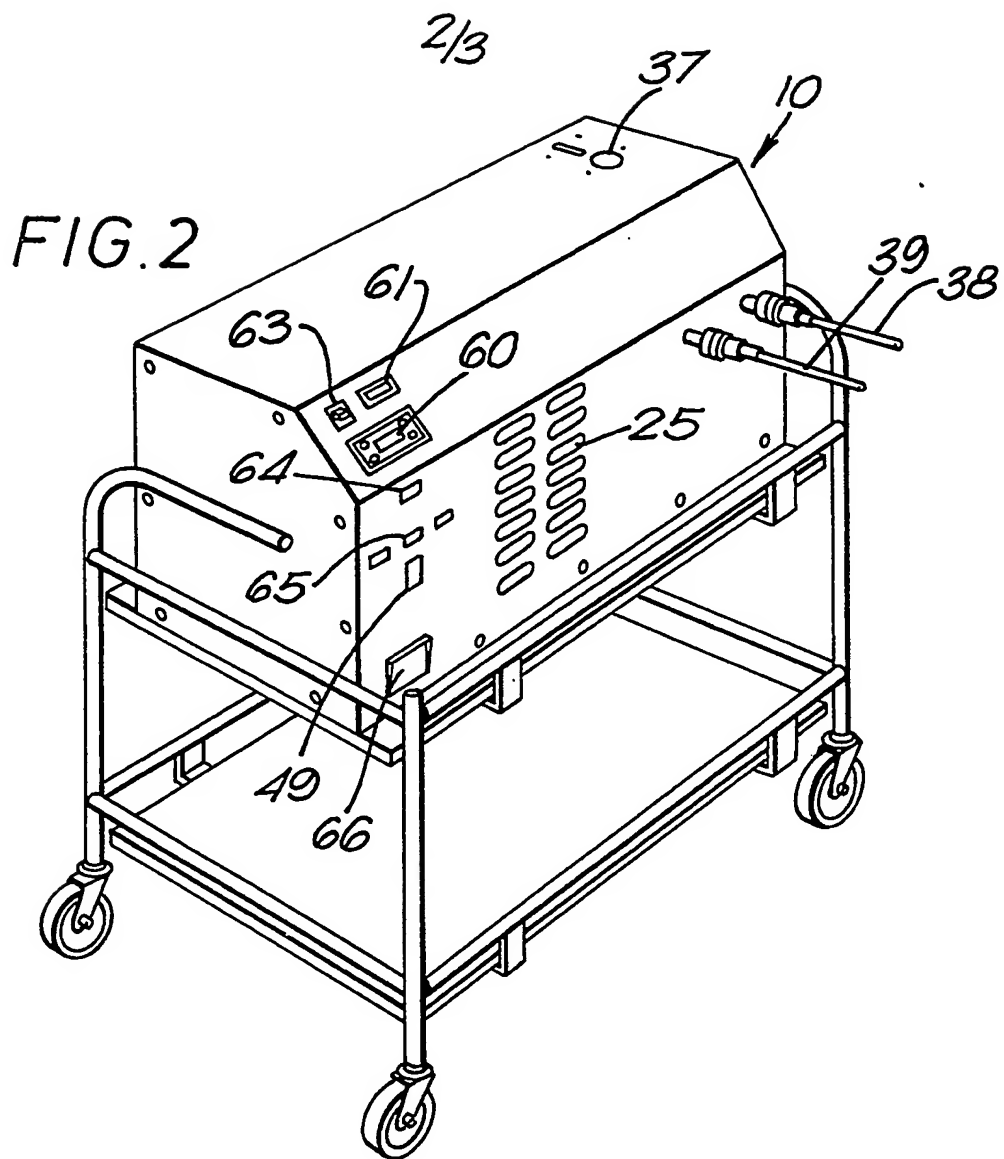
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## (54) Cooling or heating arrangements

(57) An arrangement suitable for cooling a limb comprises a cooler 30 supplying cooling fluid to a flexible bag 50 or bandage for application to the limb. The bag or bandage incorporates a sensor for detecting the temperature of the skin and using this to control the cooling effect of the cooler by means of a control system 40. Apparatus for heating a limb is also disclosed.







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FIG. 4a

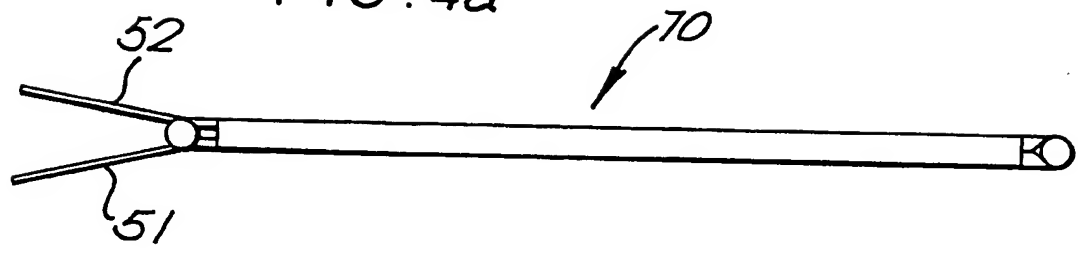


FIG. 4b

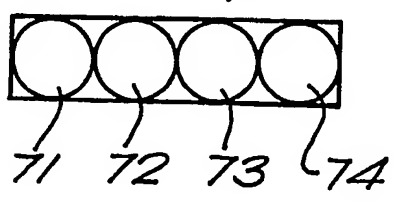


FIG. 4c

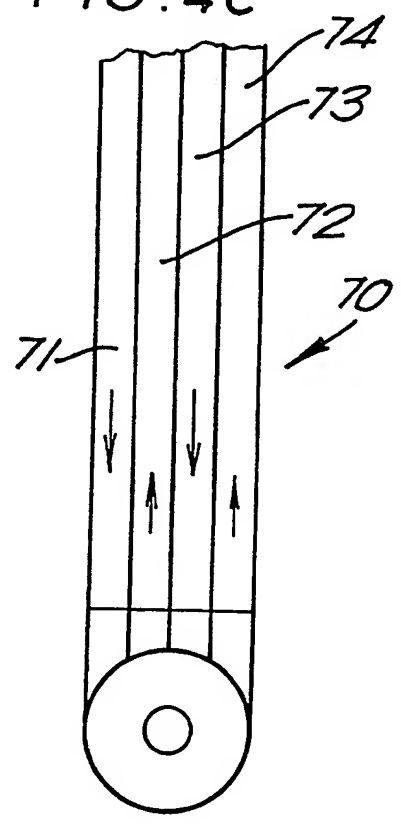


FIG. 4e

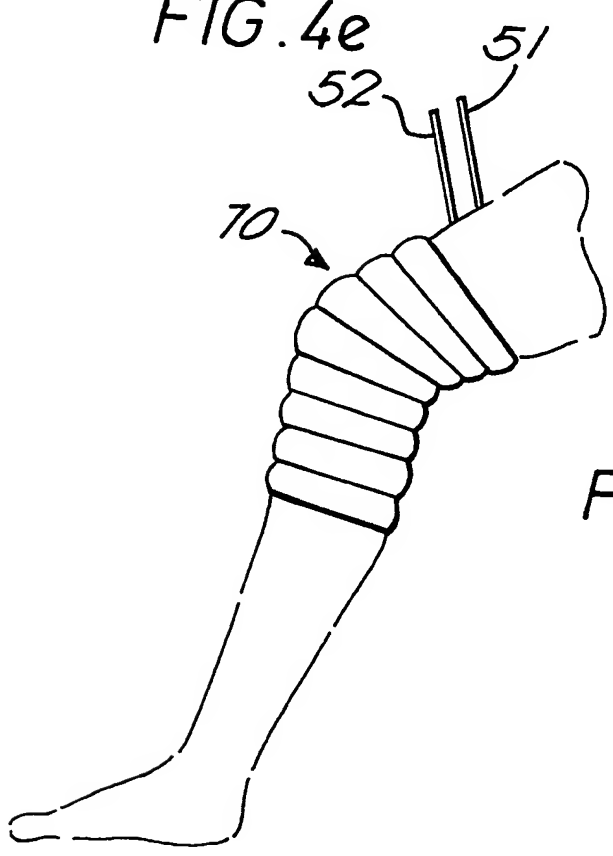
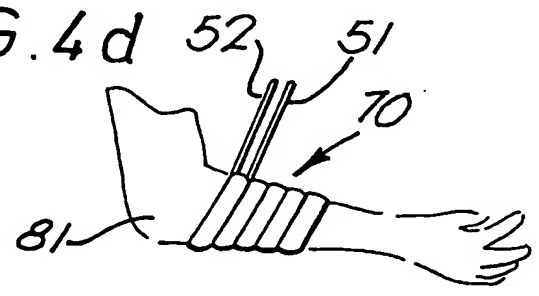


FIG. 4d



Cooling or Heating Arrangements

The present invention relates to cooling or heating arrangements and more particularly to an arrangement for use in medical treatment for heating or cooling part of the body, especially part of a limb.

5

Cooling of a limb to below normal body temperature is known to relieve the effects of muscle compartments being filled with excess fluid following injury. This so-called compartment syndrome otherwise results in  
10 excessive pressure on nerves and blood vessels with consequent pain and further damage caused by lack of blood supply. For optimum treatment and to avoid possible injury due to overcooling it is also known that the extent of cooling must be limited.

15

There are also other situations in which it is desirable to apply heat to a limb.

It is known to apply local cooling to an injured limb  
20 e.g. by using ice bags, cold packs, cold immersion, refreezable bags and chlorofluoromethane mixtures. These, however, are relatively coarse treatments with no precise control of temperature and are also relatively labour-intensive.

25

The present invention seeks to overcome or reduce at least one of the above problems.

According to a first aspect of the present invention  
30 there is provided a cooling arrangement comprising a cooler, flexible means for containing a cooling fluid which can be applied to a member to be cooled, and means for circulating a cooling fluid from the cooler to the containing means under the control of means for  
35 sensing the temperature of the member to be cooled.

The containing means may comprise a flexible bag. The bag may have retaining means for retaining the bag in a wrapped position around the limb. The retaining means may be in the form of straps and may incorporate a reusable touch and close fastener.

The bag may be formed from a plastics material and the retaining means comprises straps formed integrally with the bag. Advantageously at least part of the plastics material is transparent.

The fluid is preferably water.

The sensor may be located against the limb with a thermally insulating pad forming a thermal break between the sensor and the heat exchanger bag. The sensor may comprise a thermistor, thermocouple or other suitable device.

Alternatively the containing means may comprise a flexible bandage incorporating fluid-carrying tubes.

The limb cooler is designed for the reduction of local body temperature in the vicinity of a fracture with a view to improving the prognosis for patients by reducing swelling and improving blood circulation.

Specifically it has been shown to be particularly effective in the treatment of compartment syndrome. Initial symptoms of compartment syndrome are considerable pain and tenderness to touch or movement of the affected limb, followed by loss of sensation and motor function in the extremity. Treatment is initially to remove any restricting bandages or plasters followed, if necessary, by fasciotomy or epimysiotomy.

These measures will clearly interfere with concomitant fracture treatment as well as being an emergency operation which may be required at short notice.

5

It has also been found that compartment syndrome may affect traction treatment or unstable fractures. This is because when traction is applied, the compartment pressure is increased above the base level pre-existent  
10 in the compartments and may go from a non-ischaemic to an ischaemic level. This increase is proportional to the applied traction load.

More serious conditions may arise from failure to  
15 arrest compartment syndrome to safe levels. Prolonged ischaemia may lead to muscle infarction or necrosis.

Although nerves may possibly regenerate over time, the necrotic muscle will be replaced by fibrous tissue  
20 which contracts causing contracture.

The lowering of the limb temperature has three effects which are positive in this respect.

25 a. If the surface of the limb is cooled then a profound vasoconstriction will occur reducing the capillary pressures in the limb and reducing oedema.

b. Hypothermic tissue has a much reduced requirement  
30 for oxygen and so ischaemia as may develop will be less damaging to the tissue than at normal temperature.

c. The analgesic results of lowering the limb temperature will reduce the severe pain which  
35 accompanies compartment syndrome.

An additional advantage of cold as a therapeutic measure is that it inhibits the development of infection in any damaged tissue.

5 In a preferred arrangement, the affected limb is surrounded by a flexible plastic heat exchange bag through which water at approximately 5 degree C is passed. This process effects localised cooling of the tissue down to a pre-set temperature. A control unit  
10 then maintains this temperature by continuously monitoring the skin temperature and adjusting the water flow accordingly.

15 In another preferred embodiment, the affected limb is surrounded by a flexible bandage having a plurality of interconnected fluid channels extending therealong.

Once set, the unit requires the minimum of monitoring by nursing staff. It will display at all times (1) the actual skin temperature (2) the elapsed time of the  
20 treatment and (3) the activity of the water recirculation and refrigeration system.

25 Apart from the application in local trauma, the cooling device can be used post-operatively following open reduction and internal fixation of upper and lower limb fractures and also after routine surgery such as total knee replacements to prevent swelling.

30 The physiological effects of hypothermia are vasoconstriction, reduction of muscular impulse responses, blockage of the neuromuscular junction and reduction in the conduction velocity of peripheral nerves. Clinically these produce analgesia, reduction  
35 of muscle spasm without changes in muscular strength and endurance, reduction of local oedema and inflammation and reduction of local metabolic rate.

The precapillary sphincter is sensitive to cold. Between 4 Deg.C and 16 Deg.C the precapillary sphincter constricts, below 4 Deg.C the precapillary sphincter dilates. Cooling, therefore, within the range of  
5 16 Deg.C to 4 Deg.C can prevent bleeding and tissue oedema.

In severe injuries as those seen in the trauma units at hospitals, local cooling is recommended to be applied  
10 to open fractures for a period of no less than 3 days at a temperature of between 14 Deg.C and 20 Deg.C. This provides analgesia, reduces the metabolic requirements and hence the damage to tissue and inhibits the development of oedema. By reducing the  
15 metabolic requirements the need for oxygen in the tissues and muscles is therefore diminished, but their viability is preserved.

In addition local cooling can be applied post  
20 operatively to the upper and lower extremities and it can also be used by physiotherapists.

According to a second aspect of the present invention there is provided a bag made of flexible material  
25 having a fluid inlet and a fluid outlet with means defining within the bag a tortuous path for fluid flowing from said inlet to said outlet, a temperature sensor, and a thermally insulating piece of material between said bag and said sensor.

30

The bag is preferably a plastics material with one major wall being transparent and the other being covered with textile material. Lengths of plastics tubing are preferably provided integrally connected to  
35 said inlet and outlet.

According to a third aspect of the present invention there is provided a bandage made of flexible material having a fluid inlet and a fluid outlet, and a plurality of tubes connected thereto and defining one  
5 or more return paths along the length of the bandage.

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, of which:

10

Fig.1 is a schematic view of a cooling arrangement in accordance with a first embodiment of the present invention;

15 Fig.2 is a perspective view of a cooler unit of the arrangement of Fig.1;

Fig.3 is an enlarged view of a modified bag;

20 Fig 4a is a general view of another flexible containing means in the form of a bandage;

Fig. 4b is an enlarged cross-sectional view of the bandage of Fig. 4a;

25

Fig. 4c is an enlarged view of the right-hand end of the bandage of Fig. 4a; and

Figs. 4d and 4e are views of the bandage of Figs. 4a-c  
30 being applied to an arm and a leg respectively.

Referring to the drawings, a cooler unit 10 comprises a refrigeration system 20, a cooling water circulation system 30 and an electronic control system 40. The  
35 refrigeration system 20 comprises a compressor 21 and a condenser 22 over which air is sucked by a condenser fan 23. The air passes over the compressor before

exiting at the rear of the unit. Both air inlet and outlet are via louvres 25 cut into the panel work.

The water circulation system 30 comprises a tank 31  
5 made of plastics material and having a filler cap 37,  
Fig.2. The refrigeration system 20 cools copper  
evaporator coils which are mounted around the inside of  
the walls of tank 31. When the tank is full of water  
22, the evaporator coils 33 of the refrigeration system  
10 produce a reserve of chilled water inside the tank.  
The temperature of this water is controlled by a  
submerged thermostat within the water tank. The water  
contained within the water tank is agitated, via an  
electrically operated submerged propeller 35. The  
15 temperature of the water is therefore normally  
within a range of 2 Deg.C to 4 Deg.C.

The propeller 35 is actually part of a magnetic drive  
semi-submersible pump, taking chilled water from within  
20 the tank through to an outlet connector 38 on the  
outside of the tank. The connector 38 is connected to  
plastic tubing 51, through a flexible plastic bag 50  
containing water channels and returning via plastic  
tubing 52 to an inlet connector 39. The connectors  
25 38,39 incorporate automatic stop valves to allow bags  
50 to be disconnected from the unit without spillage of  
water. The returned water goes directly back into the  
water tank 31. Thus the unit 10 creates chilled water  
and circulates it through a flexible bag 50 which is  
30 attached in normal use to part of a human body  
(normally an arm or leg).

The temperature of the limb to which the bag 50 is  
attached is controlled by switching on and off the  
35 water recirculation pump 35. This switching is  
controlled by a bio-feedback system. A temperature  
sensor 41 is attached to the skin underneath the bag

50. It is insulated by a small gauze/cotton wool patch  
43 on its upper side to prevent it sensing the  
temperature of the bag rather than the skin. Sensor  
41, which may be a thermistor device, is connected via  
5 wires 48 to an input 49 of the control system 40 where  
the skin temperature reading is read by a micro-chip  
controlled thermostat device 42. This device is pre-  
set by the operator to a desired temperature. The  
chilled water will flow through the bag 50 when the  
10 temperature that the machine reads is in excess of the  
desired temperature. The chilled water flowing  
through the bag will therefore continue to bring down  
the limb temperature. When the limb temperature is  
read as equal to the desired temperature the water flow  
15 will stop. The limb will begin to warm again due to  
the circulation of warmer blood. The control system  
40 switches on the pump again when the limb temperature  
reads 1 Deg.C above the desired temperature. Thus the  
cooling of the limb can be thought of in two stages,  
20 viz (i) bringing the limb temperature down from normal  
to the desired cooled temperature and (ii) maintaining  
the desired cooled temperature within a differential of  
about 1 Deg.C for an indefinite period.

25 The unit 10 also comprises an electronic temperature  
setting and indication module 60, an indicator 61 of  
the duration of the treatment time, an on/off switch  
63, an alarm indicator light 64, further indicator  
lights 65 including a "power-on" light, and a circuit  
30 breaker 66.

The unit 10 also includes means for setting a  
temperature below which, for safety reasons, the skin  
should not fall. If the skin sensor 41 ever reaches  
35 this value, means are provided for automatically  
switching off the machine. An audible alarm may also  
be provided which is triggered when the limb

temperature falls below the alarm threshold.

Bag 50 has one major wall made of transparent medical PVC material with the other major wall being of a plastic material covered with a white textile material. The white textile material serves to keep condensation to a minimum. The bag is manufactured integrally with plastic tubes 51,52, which are typically 1 metre long, and the walls of the bag may be sealed together along selected lines to define a tortuous path for the water as it flows from the outlet of tube 51 to the inlet of tube 52. The bag is retained in position on the limb by means of separate reusable straps incorporating touch and close fasteners.

15

The bag 50 is conveniently arranged to be supplied as a separate disposable item. A fresh bag is used for each patient and is supplied in a sterilised condition with a separate disposable stick-on patch 43.

20

An advantage of the above-described arrangement is that it permits immediate and precisely-controlled cooling of an injured limb, particularly in the vicinity of a fracture. The patient does not require the constant attention of medical staff. By making both the bag 50 and the plastic tubing 51, 52 as a disposable unit there is no possibility of warm stagnant water building up when the unit is not in use.

30 Numerous modifications can be made to the above-described arrangement. For example the temperature sensor 51 may instead detect the temperature of the skin to one side of bag 50, or of the water inside the bag 50 or inside tubing 51 or 52, or indeed there may be no temperature feedback at all. As will be appreciated these alternatives represent decreasingly effective methods of treatment. Also the water can be

passed through the system once and then discharged, though this uses more energy.

The arrangement may have various modes of operation. For example it may be set to operate for a pre-set period and then switch off automatically. It may include devices for monitoring limb temperature, flow rate and source temperature of the cooled water etc. and may have means responsive to the crossing of a threshold of any of these devices to switch off automatically and/or to operate an alarm. In one display arrangement the actual temperature of the limb is normally displayed; upon activation of a switch on the unit, however, the set temperature is displayed for checking purposes.

In the treatment of injured limbs to prevent compartment syndrome the apparatus will ideally provide cooling of the limb to between 14 and 18 degrees Celsius. It is desirable for cooling to be applied as early as possible after injury. Normally, the limb cooler is for use in hospitals operating off a 240 volt a.c. supply; however the apparatus could be portable and capable of operation from 12 volts d.c. supply so as to be usable in an ambulance.

Similar apparatus may be used to provide heating of a limb, the differences being that a water heater be used instead of a water cooler and the function of the controller reversed to turn on the pump whenever the limb temperature falls below a threshold temperature intermediate the source temperature and the normal body temperature.

The modified bag 150 shown in Fig. 3 has the tube connections at opposite ends thereof. It is arranged to be non-disposable and thus incorporates integral

straps 155 with touch and close hooked fasteners 156. The tortuous path 157 for the water within the bag can be seen. Wires 148 connect the temperature sensor (not shown) under pad 143 to the control system of the unit.

Although described above in connection with cooling an arm, arrangements in accordance with the present invention can be used to control the temperature of the shoulder, the feet or any other part of the human body, or part of an animal, or indeed of any desired article. The shape of bag 50 can be configured as desired for any of these purposes.

In the modification of Fig. 4, the flexible bag 50 is replaced by a flexible bandage 70 of rubber or other elastomeric material. The bandage is conveniently approximately 5 meters long and comprises four internal tubes 71, 72, 73, 74 arranged side by side for the passage of cooling (or heating) fluid. Integrally-formed inlet and outlet tubes 51, 52 are connected to the system 30 as disclosed above. Inlet tube 51 is connected to internal tube 71 and outlet tube 52 is connected to internal tube 74.

At the remote end of the bandage there is provided a circular plastics button member 76 which serves to operatively connect tube 71 to tube 72, and tube 73 to 74. At the end adjacent tubes 51, 52 the bandage is provided with further means for connecting tube 72 to tube 73. Thus cooling fluid admitted to inlet 51 passes along the length of the bandage four times before it emerges at outlet 52.

Fig. 4d shows bandage 70 applied to an arm 81. The individual wraps of the bandage are applied side-by-side rather than overlapping. This provides a complete coverage of the arm by the cooling surface of the bandage. Either side of the bandage may be used for cooling.

Fig. 4e shows bandage 70 applied to a leg. The nature of the bandage allows cooling above and below the knee whilst allowing it to articulate which is important following knee surgery.

The bandage 70 may incorporate the same features as the previously-described bags 50, 150. Thus its surface can be provided with an adhesive strip or adhesive patches and/or the bandage may have tapes or straps for retaining it to a limb. It also preferably comprises a temperature sensor, thermally insulated from the rest of the bandage. The bandage may be wholly or partly of transparent material. The individual tubes may be moulded or adhered together to form the bandage.

For bags 50, 150 and bandage 70, non-integral tubes 51, 52 may be provided if desired.

For cooling the face or another part of the head the fluid-containing means may be in the form of a mask with fluid-carrying means. The material of the mask is not necessarily flexible like the bag and bandage.

CLAIMS

1. A cooling arrangement comprising a cooler, flexible means for containing a cooling fluid which can be applied to a member to be cooled, and means for circulating a cooling fluid from the cooler to the  
5 containing means under the control of means for sensing the temperature of the member to be cooled.
2. A cooling arrangement according to claim 1, wherein the containing means comprises a flexible bag  
10 with retaining means for retaining the bag in wrapped position around the limb.
3. A cooling arrangement according to claim 1, wherein the containing means comprises a flexible  
15 bandage comprising a plurality of fluid-carrying tubes extending therealong and communicating with each other.
4. A cooling arrangement according to any preceding claim, wherein at least part of the flexible containing  
20 means is transparent.
5. A cooling arrangement according to an preceding claim, wherein the flexible containing means incorporates a temperature sensor, thermally-insulated  
25 from the rest of the containing means.
6. A cooling arrangement substantially as herein described with reference to Figs. 1 and 2, or to Fig. 1, as modified by Fig. 3 or Fig. 4, and Fig. 2 of the  
30 accompanying drawings.
7. A method of cooling a member employing an arrangement according to any preceding claim.
- 35 8. A heating arrangement comprising a cooling

arrangement according to any of claims 1 to 6 modified in that the cooling fluid is replaced by a heating fluid.

9. A method of heating a member employing an arrangement according to claim 8.

10. A bag made of flexible material having a fluid inlet and a fluid outlet with means defining within the bag a tortuous path for fluid flowing from said inlet to said outlet, a temperature sensor, and a thermally insulating piece of material between said bag and said sensor.

11. A bag substantially as herein described with reference to Fig. 3 of the accompanying drawings.

12. A bandage made of flexible material having a fluid inlet and a fluid outlet, and a plurality of tubes connected thereto and defining one or more return fluid paths along the length of the bandage.

13. A bandage according to claim 12 comprising a temperature sensor and a thermally insulating piece of material between said bandage and said sensor.

14. A bandage substantially as herein described with reference to Fig. 4 of the accompanying drawings.

**Patents Act 1977**  
**Examiner's report to the Comptroller under**  
**Section 17 (The Search Report)**

Application number

GB 9301707.7

**Relevant Technical fields**

(i) UK Cl (Edition L ) A5R (REH)

(ii) Int Cl (Edition 5 ) A61F 7/00

Search Examiner

N A FRANKLIN

**Databases (see over)**

(i) UK Patent Office

(ii)

Date of Search

28 APRIL 1993

Documents considered relevant following a search in respect of claims 1-9

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X	EP 0158470 A1 (C.C.C) - Note Claim 2	1 at least
X	EP 0039443 A1 (STEINGRAF) - Note entire document	1 at least
X,P	US 5097829 (QUISENBERRY) - 24 March 1992 Note Figure 1; column 4 line 19 - column 5 line 15	1 at least
X	US 4184537 (SAUDER) - Note entire document	1 at least
X	US 4170998 (SAUDER) - Note Claim 1	1 at least
X	US 3967627 (BROWN) - Note Claim 1	1 at least

Category	Identity of document and relevant passages	Relevant to claim(s)

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